

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

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Submitted electronically via A.Policy@PalmettoGBA.com

**SUBJECT: LCD DL34555-Draft LCD for Non-Covered Category III CPT Code 0398T:  
MRgFUS stereotactic lesion ablation**

Dear Dr. Garrett,

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the American Association of Stereotactic and Functional Neurosurgery (ASSFN) appreciate the opportunity to comment on the proposed local coverage determination (LCD) titled "Non-Covered Category III CPT Codes: DL34555," specifically as related to CPT code 0398T (MRgFUS stereotactic lesion ablation for the treatment of movement disorders). Based on the current literature, we request that Palmetto cover unilateral MRgFUS thalamotomy for patients with essential tremor who cannot be controlled with medication therapy.

Approved procedures for treatment of essential tremor currently include:

- CPT 61720 *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus;*
- CPT 61863 *Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array;*
- CPT 61867 *Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array; and the associated "additional array" codes (CPT +61864, CPT +61868).*

All of these codes require passing a probe through brain tissue, and in the case of CPT 61720, also require creating a lesion with a radiofrequency probe.

A recent Level I double-blinded, randomized, sham-controlled trial published in the *New England Journal of Medicine* (Elias, Lipsman et al., 2016) demonstrated clinically meaningful benefit from MRgFUS thalamotomy for essential tremor patients that were refractory to medical therapy. The major findings from this study, which led to FDA approval in July 2016, include:

- Contralateral upper limb tremor score (maximum 32 points), the primary study endpoint, was significantly improved following tcMRgFUS thalamotomy than from sham procedures at three months ( $p < 0.001$ ). Mean contralateral hand tremor score improved by 47% following MRgFUS

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thalamotomy ( $18.1 \pm 4.8$  at baseline vs.  $9.6 \pm 5.1$  at 3 months) and did not change in the control cohort who received sham procedure ( $16.0 \pm 4.4$  at baseline vs.  $15.8 \pm 4.9$  at three months).

- The improvement from baseline resulting from MRgFUS persisted throughout the study period with mean, contralateral hand tremor score of  $10.9 \pm 4.9$  ( $p < 0.001$ ) at 12 months, a 40% improvement.
- An unblinded cohort of 21 subjects (19 sham crossover and two prior incomplete thalamotomies) was treated after the three month blinded assessment period. Their mean, contralateral hand tremor score improved by 55% at 3 months ( $16.5 \pm 4.2$  to  $7.4 \pm 3.9$ ,  $p < 0.001$ ) and by 60% at 6 months ( $16.5 \pm 4.2$  to  $8.0 \pm 3.9$ ,  $p < 0.001$ ).
- Regarding safety, there were no serious peri-procedural adverse events, and the one serious adverse event was a moderate thumb paresthesia that persisted to cause the patient some difficulty. All other adverse events were categorized as mild or moderate with the majority being transient and the most common being sensory paresthesias (14% at 12 months) and gait disturbance (9% at 12 months).

Transcranial MRgFUS is an alternative to the current open surgical methods of treating essential tremor; it differs from other surgical methods because it does not involve incising the skin, opening the skull, and passing surgical instruments through brain tissue. Radiofrequency thalamotomy and MRgFUS thalamotomy both create a thermocoagulation lesion in the thalamus.

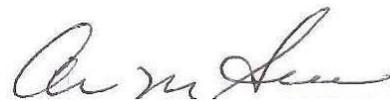
With MRgFUS now supported by level 1 medical evidence as having similar treatment effect to currently approved procedures for treatment of essential tremor, and a safety profile superior to historical invasive radiofrequency thalamotomy, we recommend Palmetto cover unilateral MRgFUS thalamotomy for patients with essential tremor who cannot be controlled with medication therapy, and that Palmetto GBA remove CPT 0398T from the list of non-covered codes within Group 1 paragraph of the draft LCD.

The AANS and CNS appreciate the opportunity to comment on this proposed LCD. If you have any questions or need further information, please feel free to contact us.

Sincerely,



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